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PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

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Confirmation No.

9366

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October 24, 2003

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Examiner:

George C. Manuel

Group Art Unit:

3762

Docket No.:

1023-284US01

Title:

Z-AXIS ASSEMBLY OF MEDICAL DEVICE PROGRAMMER

DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

We, Alex C. Toy and John W. Forsberg, declare as follows:

- 1. We are named inventors in above-referenced Patent Application Serial No. 10/693,007.
- 2. We are employees of Medtronic, Inc., the Assignee of record for the present application.
- 3. The above-referenced Patent Application Serial No. 10/693,007 claims priority to Provisional Patent Application Serial No. 60/508,511 filed October 2, 2003.
- 4. More than one year prior to October 2, 2003, Medtronic, Inc. requested that Benchmark Electronics, Inc. manufacture 222 programmers for a medical device pursuant to assembly drawings shown in Exhibit A. Exhibit A is a two-page document assigned document

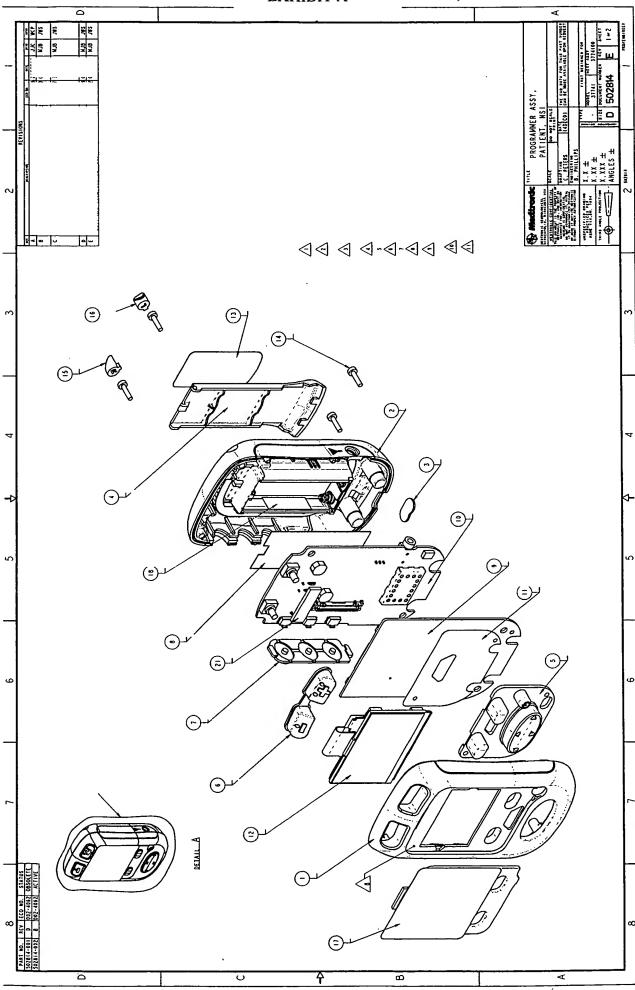
number 502814 and relates to a programmer with model number 37741 ("Model 37741 programmer"). On sheet 1, Exhibit A illustrates an assembly view of a Model 37741 programmer for a medical device. On sheet 2, Exhibit A illustrates an assembled view of a Model 37741 programmer for a medical device. Medtronic Inc. confidential and proprietary information has been redacted from Exhibit A.

- 5. More than one year prior to October 2, 2003, Benchmark Electronics, Inc. manufactured 222 Model 37741 programmers pursuant to the request from Medtronic, Inc.
- 6. At least 89 of the 222 Model 37741 programmers manufactured by Benchmark Electronics, Inc. more than one year prior to October 2, 2003 were used for experimental purposes, as evidenced by Exhibits B-D. Exhibit B is a forty-nine page document assigned document number 288117-70205 and entitled, "Neuro Patient Programmer Platform Electrical DVT Report." Exhibit C is a one page screen print of an internal electronic document storage and retrieval system at Medtronic, Inc., which indicates that document number 288117-70205 (Exhibit B) was modified on October 7, 2002 and June 28, 2003. Exhibit D is a twenty-nine page document entitled, "DVT Test Data for 288117-70020," and summarizes the results of tests conducted in May 2002 and June 2002. Medtronic Inc. confidential and proprietary information has been redacted from Exhibits B and D.
- 7. The remainder of the 222 Model 37741 programmers manufactured by Benchmark Electronics, Inc. more than one year prior to October 2, 2003 were not used for the tests reflected in Exhibits B and D and were used internally by Medtronic, Inc. employees for development purposes.
- 8. In view of this Declaration and the content of Exhibits A-D, it is clear that the 222 Model 37741 programmers manufactured by Benchmark Electronics, Inc. were not "in public use or on sale in this country, more than one year prior to the date of application for patent in the United States" under 35 U.S.C. § 102(b).

We hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date:_	Oct. 4, 2006	Signed: alex C. Toy	
	•	Alex C. Toy	

Date: Oct 4,2006 Signed: John W. Forsberg



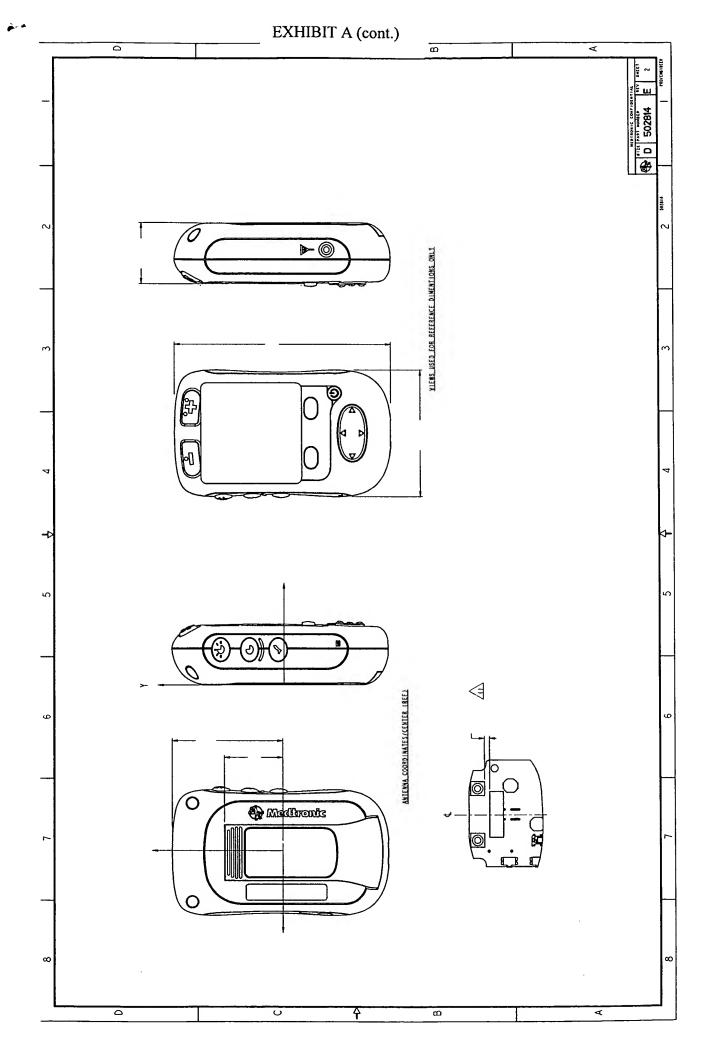


EXHIBIT B

Medtronic	Neurological	Document Number 288117-70205	Rev/Version 1.0	Sht 1 of 49
Title: Neuro Patient Programmer Pla	atform Electrical DV	T Report		

Revision History:

Revision	Comments
1.0	Initial release for routing



Neurological

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1 INTRODUCTION

This document is the electrical Design Verification Test (DVT) Report for the 37741 Patient Programmer Platform.

1.1 Purpose

The purpose of this report is to document the results of test plan.

1.2 Scope

This report applies only to design verification testing of the 37741 Patient Programmer Platform.

1.3 Document Overview

This document is organized as follows:

- Section 2 contains references and definitions.
- Section 3 contains a table with the list of tests, software revisions, sample sizes, and test results.
- Section 4 contains the results of the electrical design verification tests.

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2 REFERENCES AND DEFINITIONS

This section identifies internal and external reference documents that augment the information provided in this document. It also defines terms, acronyms, and abbreviations used within the document.

2.1 Internal Medtronic References

Number	Name
120275	
215387	
288117-70040	
288117-70044	
288117-70029	
503011001	
288117-70200	

Note: Document revisions referenced in DVT Plan.

2.2 External References

Reference the PEM Electrical Specification for external specification standards.

2.3 Definitions, Acronyms, and Abbreviations

ARB: Arbitrary Waveform Generator

ARB equipment: One or more arbitrary waveform generators, used alone or in conjunction to generate sophisticated waveforms.

DUT: Device Under TestDVT: Design Verification Test

DVT Console: The test console needed to perform the tests specified herein.

ES: Electrical Specification #120275
GPIB: General Purpose Interface Bus
PEM: Patient Electronic Module

PP: Patient Programmer POR: Power On Reset

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3 Test Results Summary

Table 1 summarizes the results of all electrical design verification testing. Section 4 details each test setup, criteria, and results.

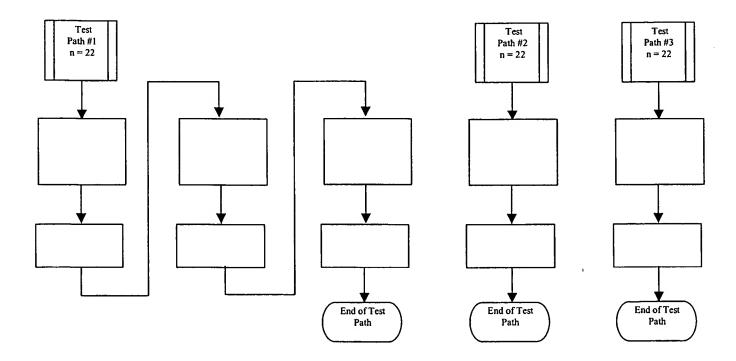
- Test data is stored as 288117-70200.
- Table 1 indicates test name, sample size, DUT software revision, Test Script Software revision, test path, and results.
- Test paths are shown in section 3.1.

Table 1

Test Name	Sample Size	DUT Software Revision	Script Software Test Revision	Test Path	Results
_	22				PASS
_	22				PASS
_	22				PASS
_	22				PASS
_	22				PASS
_	22				PASS
_	22	_			PASS
_	22				PASS
_	22				PASS
_	22				PASS
_	22				PASS
_	22			_	PASS
_	22				PASS
_	22				PASS
_	22				PASS
_	22				PASS
_	22				PASS
_	22	_			PASS
	22	_			PASS
_	22				PASS
_	22		[PASS
	1				PASS

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3.1 Test Paths



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4 ELECTRICAL TESTS

This section specifies electrical tests performed on the 37741 Patient Programmer Platform.

4.1 Power Source Tests

4.1.1 Current Drain Test

4.1.1.1 Objective

To verify the current drain meets the requirements specified in the *Power Source* section of the PEM Electrical Specification.

4.1.1.2 Method and Equipment

4.1.1.3 Test Cases

There are _ test cases for transmit using all combinations of test values below:

Parameter	Test Values	Units		
	_			
	+			
	+			

-		
	n	0
		•

There are test cases

using all

combinations of test values below:

Parameter	Test Values	Units		
		<u> </u>		
	1			

There are test cases

using two

combinations of test values below:

Parameter	Test Values	Units
	1	
	1	+
	<u> </u>	

There are total test cases.

4.1.1.4 Acceptance Criteria



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Condition)		(%)	Current Drain (mA) MAX		(mA)
Operating Condition (Ref.	Antenna	Duty Cycle (%)	V	v	v
Row A	INT				
Row B	INT				
Row C	INT			Γ -	
Row D	INT				
Row E	INT				
Row F	INT		_	_	
Row G	INT		_	Γ -	
Row H	EXT			Γ	
Row I	INT	Γ 1			
Row J	INT	[]			

Note 1:

4.1.1.5 <u>Test Setup</u>

1.

2.

3.

4.

4.1.1.6 <u>Test Procedure</u>

1.

2.

3.

4.

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4.1.1.7 <u>RESULTS</u> **PASS**

All devices met the acceptance criteria.

Operating Condition	Current Drain (mA) MAX															
Row	Spec	Min	Мах	Mean	Std Dev	Sec	Min	Max	Mean	Std Dev	Spec	Min	Max	Mean	Std Dev	
Α																\prod
В				L.			L	\mathbf{I}				\mathbf{I}	1	L.		
С			L j	L.					L.			Ι.	Ι.		L.	Ш
D				L.	<u> </u>			1	┺ .	1 _	Ш	1 -	l .	L.	L.	
E			_	L.	L 1	\perp	L	1.	L .	_	Ш		1.	L .	L.	
F				L.	Ĺĺ	╧	L	1	┖.]		Ι.	1.	L _	L.	Ш
G		_		L .	1	\perp		\perp	\perp			\perp	1 .	L.	L.	Ш
Н				L .]		Ĺ	1					1 .	l .	L.	Ш
							Ĺ	1	L .]		1	1 -	<u> </u>	L.	Ш
J					1]				<u> </u>				<u></u>			Ш

4.1.2 Supply Voltage Range Test

4.1.2.1 Objective

To verify the supply voltage range meets the requirements specified in the *Power Source* section of the PEM Electrical Specification.

4.1.2.2 Method and Equipment

4.1.2.3 Test Cases

Medtronic

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Parameter	Test Values	Units
_	T	

The

There is test case without transmit:

Parameter	Test Values	Units

4.1.2.4 Acceptance Criteria

Operating Condition	Antenna	H-Bridge Drive Duty Cycle (%)	Min operating voltage (V)
_			_

4.1.2.5 <u>Test Setup</u>

1.

2.

3.

4.

4.1.2.6 <u>Test Procedure</u>

1.

2.

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4.1.2.7 RESULTS PASS

All devices met the acceptance criteria.

Operating	Antenna	Supply Voltage Range (Volts)						
Condition	Antenna	Min	Max	Avg	Std Dev			
	_							
				-				

4.2 Input/Output Connections Tests

4.2.1 Keypad Interface Test

4.2.1.1 Objective

To verify the keypad interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.

4.2.1.2 Method and Equipment

4.2.1.3 <u>Test Cases</u>

Parameter	Test Values	Units
		Į

4.2.1.4 Acceptance Criteria

4.2.1.5 <u>Test Setup</u>

1.

2.

3.

4.2.1.6 <u>Test Procedure</u>

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3.

4.2.1.7 RESULTS PASS

All devices met the acceptance criteria.

	Keypad Interface (pass/fail)	
Tests			
	Pass	Pass	Pass
	Pass	Pass	Pass

4.2.2 Display Interface Test

4.2.2.1 Objective

To verify the display interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.

4.2.2.2 Method and Equipment

4.2.2.3 Test Cases

There are test cases using combinations of the test values below:

Parameter	Test Values	Units
	·	
<u> </u>		+

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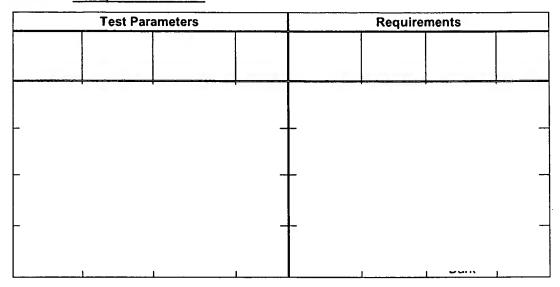
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4.2.2.4 Acceptance Criteria



4.2.2.5 Test Setup

1.

2.

3.

4.2.2.6 <u>Test Procedure</u>

1.

2.

3.

4.

4.2.2.7 <u>RESULTS</u> PASS

	Display Interface (pa	ss/fail)	
Test			
	Pass	Pass	Pass
•	Pass	Pass	Pass
-	Pass	Pass	Pass

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4.2.3 External Antenna Interface Test

4.2.3.1 Objective

To verify the external antenna interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.

4.2.3.2 Method and Equipment

4.2.3.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values	Units

4.2.3.4 Acceptance Criteria

- When an external antenna is connected, there should be no downlink from the internal antenna.
- When an external antenna is connected, the uP should detect that the antenna is connected.

External Antenna					
	Min	Max	Min	Max	Yes/No
-		• • • • • • • • • • • • • • • • • • • •			
	Γ		Γ	Γ 7	

4.2.3.5 <u>Test Setup</u>

1.

2.

3.

4.

5.

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4.2.3.6 <u>Test Procedure</u>

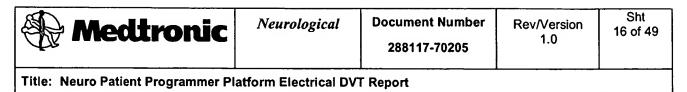
1.

2.

3.

4.

4.2.3.7 <u>RESULTS</u> PASS



4	Exter	nal An	tenna	Interfa	ce (A/m)						
Test	Min	Max	Mean	Std dev	Min	Мах	Mean	Std dev	Min	Max	Mean	Std dev
A	Σ	Σ	Σ	<u>8</u>	Σ	Σ	Ž	क	Σ	Σ	Ž	L

4.2.4 Infrared Port Interface Test

4.2.4.1 Objective

To verify the infrared port interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification. [PTPROG_PEMT-0006:7]

4.2.4.2 Method and Equipment

4.2.4.3 <u>Test Cases</u>

There are test cases using all combinations of test values below:

Parameter	Test Values	Units

4.2.4.4 Acceptance Criteria

All	All	None

4.2.4.5 <u>Test Setup</u>

1.

2.

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3.

4.2.4.6 Test Procedure

1.

2.

3.

4.

4.2.4.7 RESULTS PASS

All devices met the acceptance criteria.

	Infrare	d (pass/	fail)						
Voltage (V)									
_	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
_	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

4.2.5 Audio Transducer Test

4.2.5.1 Objective

To verify the audio transducer meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.

4.2.5.2 Method and Equipment

4.2.5.3 Test Cases

There are test cases using all combinations of test values below:

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Parameter	Test Values	Units

4.2.5.4 Acceptance Criteria

11.0	·	

4.2.5.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.

4.2.5.6 <u>Test Procedure</u>

- 1.
- 2.
- 3.
- 4.

4.2.5.7 RESULTS PASS

All devices met the acceptance criteria.

Aud	lio Tr	ansd	ucer (di	3 S	PL)						· · · · ·		
Min	Мах	Mean	Std dev		Min	Max	Mean	Std dev	Min	Max	Mean	Std dev	
						 	-	-	_			-	

4.2.6 Manufacturing/Test Interface Test

Manufacturing requirements defined in Test Specification, Patient Programmer, 215387.

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4.3 Internal Resources Tests

4.3.1 Memory Test

4.3.1.1 Objective

To verify the internal memory resources meet the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.1.2 <u>Method and Equipment</u>

4.3.1.3 Test Cases

4.3.1.3	1681 Cases			
There are	e test cases i	using all combi	nations of test value	es below:
	Parameter	Test Value	es .	Units
4.3.1.4	Acceptance C	<u>Criteria</u>		
		All	Pass]
4.3.1.5	<u>Test Setup</u>			
1.			•	
2.				
3.				
J.				
4.3.1.6	Test Procedu	ro.		
1.	<u>rest Frocedu</u>	<u>16</u>		
2.				
3.				
4.				

4.3.1.7 RESULTS PASS

·	Memory (pass/fail)		
Test			
	Pass	Pass	Pass
-	Pass	Pass	Pass
_	Pass	Pass	Pass

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4.3.2 Real-Time Clock Backup Test

4.3.2.1 Objective

To verify the real-time clock backup meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.2.2 Method and Equipment

4.3.2.3 Test Cases

There is one test case below:

Parameter	Test Value	Units

4.3.2.4 Acceptance Criteria

Test Case	Min Time w/o power (min)

4.3.2.5 Test Setup

1.

2.

3.

4.3.2.6 <u>Test Procedure</u>

1.

2.

3.

4.

5.

4.3.2.7 RESULTS PASS

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	Real-Time Backup (pass/fail)						
Test							
	Pass	Pass	Pass				

4.3.3 Real-Time Clock Accuracy Test

4.3.3.1 Objective

To verify the real-time clock accuracy meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

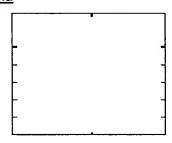
4.3.3.2 Method and Equipment

4.3.3.3 Test Cases

There are test cases (actually measurement points) using all combinations of test values below:

Parameter	Test Value	Units

4.3.3.4 Acceptance Criteria



4.3.3.5 <u>Test Setup</u>

1.

2.

4.3.3.6 <u>Test Procedure</u>

1.

2.

4.3.3.7 RESULTS PASS

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	Real Time	e Clock Ad	ccuracy (sec	conds)	
Ľ.		<u> </u>			
-	 	 	+	-	+
-	-		+		+
-	-	<u> </u>	+		

4.3.4 A/D Measurements Test

4.3.4.1 Objective

To verify the A/D measurement accuracy meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.4.2 Method and Equipment

4.3.4.3 <u>Test Cases</u>

There are test cases using the test values below:

Parameter	Test Values	Units

4.3.4.4 Acceptance Criteria

A/D Voltage	Test Value	Max Error (%)

4.3.4.5 Test Setup

1.

2.

3.

4.

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5.

4.3.4.6 <u>Test Procedure</u>

1.

2.

3.

4.

4.3.4.7 <u>RESULTS</u> **PASS**

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		A/D	Mea	suren	nent (% l	ERI	ROR)		<u> </u>					
			Aml	oient 7	remp				v Tem	р		Hig	h Ten	ıp qı
Input	Level	Min	Max	Mean	Std dev		Min	Max	Mean	Std dev	Min	Max	Mean	Std dev
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-	-	-			_	Н	-			+	+			+
-		-			-		-			+	†			+
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†	-	-			-	H	-			+	†			+
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<u> </u>	-	 			-	\vdash	-			+	†			+

4.3.5 D/A Control Voltages Test

4.3.5.1 Objective

To verify the D/A accuracy meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.5.2 Method and Equipment

4.3.5.3 <u>Test Cases</u>

There are test cases using all combinations of test values below:

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Parameter	Test Value	Units

4.3.5.4 Acceptance Criteria

D/A Voltage	Measurement point	Max % Error

4.3.5.5 <u>Test Setup</u>

1.

2.

3.

4.

4.3.5.6 Test Procedure

1.

2.

3.

4.3.5.7 <u>RESULTS</u> **PASS**

All devices met the acceptance criteria.

:	D/A Control Voltage (% ERROR)		
	-	-	
-	-		
}-	+	+	
Ľ		<u></u>	
L	<u> </u>	Ţ	

4.4 Transmit Telemetry (Downlink) Tests

4.4.1 Magnetic Field Intensity Test

4.4.1.1 Objective

To verify downlink magnetic field intensity meets the requirements specified in the *Transmit Telemetry (Downlink)* section of the PEM Electrical Specification.

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4.4.1.2 <u>Method and Equipment</u>

			-	
4.4.1.3	Test Cases			
There are	e test cases at	kHz using all combi	nations of test val	ues below
- - -	<u> </u>			
4.4.1.4	Acceptance Criter	<u>ria</u>		
4.4.1.5 1. 2. 3. 4.	<u>Test Setup</u>			
5.				
4.4.1.6 1. 2.	<u>Test Procedure</u>			

3.

4.

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5.

4.4.1.7 <u>RESULTS</u> PASS

All devices met the acceptance criteria.

	Magnetic Field Intensity (A/m)		
	·	•	_
E	<u> </u>		-
-	+		
L	<u>+</u>		_
-	+		_

4.4.2 Burst Characteristics Test

4.4.2.1 Objective

To verify downlink burst characteristics of width, rise time, fall time, frequency, and overshoot meet the requirements specified in the *Transmit Telemetry (Downlink)* section of the PEM Electrical Specification.

4.4.2.2 Method and Equipment

4.4.2.3 Test Cases

There are test cases using all combinations of test values below:

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4.4.2.4	Accept	ance Cr	<u>iteria</u>					
		1	T	T	1	ı	1 1	
Ŀ								
Ī					·			
4.4.2.5	Test Se	etup						

- 1.
- 2.
- 3.
- 4.
- 5.

4.4.2.6 Test Procedure

- 1.
- 2.
- 3.
- 4.
- 5.

4.4.2.7 RESULTS PASS

Medtronic

Neurological

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		<u> </u>	-			-									
			Burs	t Chara			1		1	T		1	Llim	Tamp	
			Ambient Temp			-		LOW	Temp		1	Higi	Temp		
Antenna	Voltage	Test	Min	Мах	Mean	Std dev	3.74	LIMIN.	Мах	Mean	Std dev	Min	Max	Mean	Std dev
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_	-					1	±					İ			
-	J	-	 			+	+				+	+			+
		-				1	1					1			
-	-	_	-			+	+				+	+			+-
-]					‡	#				1	‡			口
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_	,	_				1	1				<u> </u>	<u>†</u>			
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-	-	_	-			+	+				+	+			+
F	•	- -				‡	#				#	‡			
-			 			+	+				+	+			+
	1		<u> </u>	<u> </u>		1	Ι.	1				<u> </u>			

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4.5 Receive Telemetry (Uplink) Tests

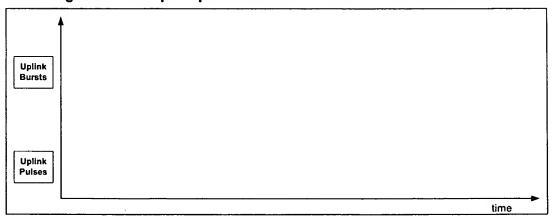
4.5.1 Detection Threshold Test

4.5.1.1 Objective

To verify uplink detection threshold (i.e. receiver sensitivity) meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.1.2 Method and Equipment

Figure 1: Example Uplink Detection Threshold Test Waveforms



4.5.1.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values	Units	
	1		
	+		
	†		
	†	-	
	1		

The supply voltage is 2.5 V.

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4.5.1.4 Acceptance Criteria

Antenna	Telemetry Type	Detection Onset (Uplink dB)	Detection Threshold (Uplink dB)	Maximum Input Level (Uplink dB)		
		Max	Max	Max		
	1			_		

4.5.1.5 <u>Test Setup</u>

1.

2.

3.

4.

5.

4.5.1.6 <u>Test Procedure</u>

1.

2.

3.

4.

4.5.1.7 <u>RESULTS</u> PASS

Antenna	Telemetry	Detection Threshold (dB)													
		Min	Мах	Mean	Std dev	Min	Max	Mean	Std dev		Min	Max	Mean	Std dev	

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Antenna		Maximum Input Level (pass/fail)							
	Telemetry		,						
		Pass	Pass	Pass					
		Pass	Pass	Pass					
		Pass	Pass	Pass					
		Pass	Pass	Pass					
	_	Pass	Pass	Pass					
		Pass	Pass	Pass					

4.5.2 Detection Margin Test

4.5.2.1 Objective

To verify uplink detection margin meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.2.2 Method and Equipment

Uplink Bursts

Uplink Pulses

Figure 2: Example Uplink Detection Margin Test Waveforms

4.5.2.3 Test Cases

There are test cases using all combinations of test values below:

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Parameter	Test Values	Units
		

4.5.2.4 Acceptance Criteria

elemetry Type	Bursts litude A1	ากล	Mai	ction rgin nk dB)	
Teleme	Data B	Ampiltude	Antenr	Min	Max
				•	

4.5.2.5 <u>Test Setup</u>

1.

2.

3.

4.

5.

4.5.2.6 <u>Test Procedure</u>

1.

2.

3.

4.

4.5.2.7 <u>RESULTS</u> PASS

All devices met the acceptance criteria.

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		Detection Margin (dB)						V								
Antenna	Telemetry	Min	Мах	Mean	Std dev		Min	Мах	Mean	Std dev		Min	Max	Mean	Std dev	
											•		-			
-				•						•		•				

4.5.3 Noise Immunity Test

4.5.3.1 Objective

To verify uplink noise immunity meets the requirements specified in the *Receive Telemetry* (*Uplink*) section of the PEM Electrical Specification.

4.5.3.2 Method and Equipment



Neurological

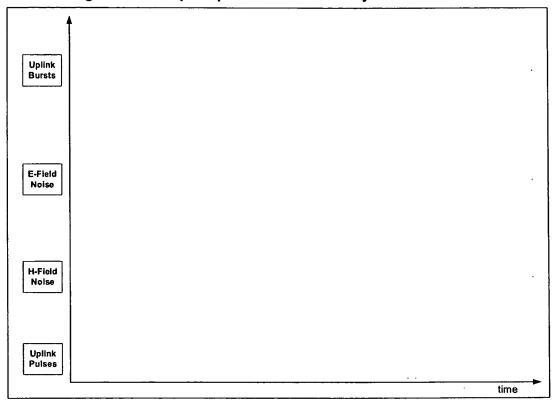
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Figure 3: Example Uplink Noise Immunity Test Waveforms



4.5.3.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values	Units
		_
		_
		_

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4.5.3.4 Acceptance Criteria

Telemetry	Uplink Level	Antenna	Min E-Noise	Min H-Noise
Type	A1 (dB)		Immunity (dB)	Immunity (dB)
				-

4.5.3.5 <u>Test Setup</u>

1.

2.

3.

4.

5.

6.

4.5.3.6 <u>Test Procedure</u>

1.

2.

3.

4.

5.

4.5.3.7 <u>RESULTS</u> PASS

All devices met the acceptance criteria.

Medtronic	Neurological	Document Number 288117-70205	Rev/Version 1.0	Sht 37 of 49							
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			Noise	Noise Immunity (dB)													
Antenna	Noise	Telemetry	Min	Мах	Mean	Std dev		Min	Мах	Mean	Std dev		Min	Max	Mean	Std dev	
-												•				_	
-																-	
-																-	
-																-	
[- -	

4.5.4 Signal Distortion Test

4.5.4.1 Objective

To verify uplink signal distortion meets the requirements specified in the *Receive Telemetry* (*Uplink*) section of the PEM Electrical Specification.

4.5.4.2 Method and Equipment

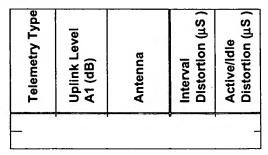
Medtronic	Neurological	Document Number 288117-70205	Rev/Version 1.0	Sht 38 of 49					
Title: Neuro Patient Programmer Platform Electrical DVT Report									

4.5.4.3 Test Cases

Test Values	Units		
•			

There are test cases for Tel A, and test cases for Tel N.

4.5.4.4 Acceptance Criteria



4.5.4.5 <u>Test Setup</u>

1.

2.

3.

4.

5.

4.5.4.6 <u>Test Procedure</u>

1.

2.

3.

4. `

4.5.4.7 <u>RESULTS</u> PASS

All devices met the acceptance criteria.

Medtronic	Neurological	Document Number 288117-70205	Rev/Version 1.0	Sht 39 of 49					
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			Signa	l Distor	tion Tel	emetry	A (us)				 		_		
Antenna	Test	Uplink (dB)	Min	Мах	Mean	Std dev	Min	Max	Mean	Std dev	Min	Max	Mean	Std dev	
-						 	-1	1	1	1					H
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			Sign	nal Distortion Telemetry N, 0's (us)													
Antenna	Test	Uplink (dB)	Min	Мах	Mean	Std dev		Min	Мах	Mean	Std dev		Min	Мах	Mean	Std dev	
-		-					,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				•	· ·		•	-	
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			Sign	al Disto	rtion T	elemetr	уN	l, 1's (u	s)								
Antenna	Test	Uplink (dB)	Min	Max	Mean	Std dev		Min	Max	Mean	Std dev		Min	Max	Mean	Std dev	
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4.5.5 Turnaround Time Test

4.5.5.1 Objective

To verify uplink turnaround time meets the requirements specified in the *Receive Telemetry* (*Uplink*) section of the PEM Electrical Specification.

4.5.5.2 Method and Equipment

4.5.5.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values	Units
	,	
J	 	

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4.5.5.4 Acceptance Criteria

Supply Voltage H-Bridge Drive Duty Cycle Turnaround

4.5.5.5 <u>Test Setup</u>

1.

2.

3.

4.5.5.6 Test Procedure

1.

- 2.
- 3.
- 4.

4.5.5.7 <u>RESULTS</u> PASS

All devices met the acceptance criteria.

	Turnaround Time (pass/fail)					
Test		• •				
	•		•			

4.5.6 Hold Drift Test

4.5.6.1 Objective

To verify the hold drift meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.6.2 Method and Equipment

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4.5.6.3 <u>Test Cases</u>

There is test case:

Parameter	Uplink Level	Units

4.5.6.4 Acceptance Criteria

Time after hold circuit enabled Max Hold Drift

4.5.6.5 <u>Test Setup</u>

1.

2.

3.

4.5.6.6 <u>Test Procedure</u>

1.

2.

3.

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7.

8.

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10

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4.5.6.7 <u>RESULTS</u> PASS

All devices met the acceptance criteria.

Hold Drift (mV)					
_	·		·		
					;
_					+

4.5.7 New-Battery FET Test

4.5.7.1 Objective

To verify that enabling the new-battery FET circuit reduces the receiver noise floor (ambient RF energy detected by the receiver circuit) when new batteries are used.

4.5.7.2 Method and Equipment

4.5.7.3 <u>Test Cases</u>

There is test case:

Parameter	Uplink Level	Units

4.5.7.4 Acceptance Criteria

Supply Voltage	New-Battery FET	RSSI Peak	
_			_

4.5.7.5 <u>Test Setup</u>

1.

2.

3.

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4.5.7.6 <u>Test Procedure</u>

1.

2.

3.

4.

5.

6.

7.

4.5.7.7 RESULTS PASS

4.6 Telemetry Performance Tests

4.6.1 Telemetry Map Area at a Fixed Distance Test

4.6.1.1 <u>Objective</u>

To verify telemetry performance in terms of map area at a fixed distance meets the requirements specified in the *Telemetry Performance* section of the PEM Electrical Specification.

4.6.1.2 Method and Equipment

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4.6.1.3 <u>Test Cases</u>

Parameter	Test Values	Units
	,	_
-		
-		· —
-		_

There are test cases.

4.6.1.4 Acceptance Criteria

IPG	Antenna	Map Area @ 5cm	
,		_	

4.6.1.5 <u>Test Setup</u>

1.

2.

4.6.1.6 <u>Test Procedure</u>

1.

2.

3.

4.

5. 6.

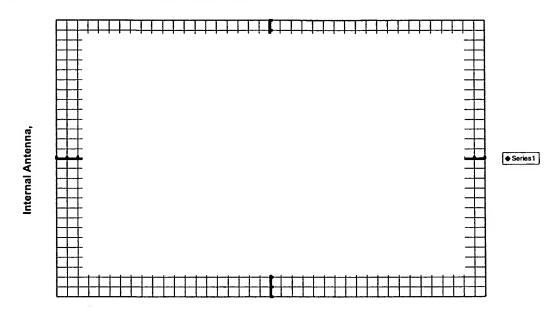
7.

8.

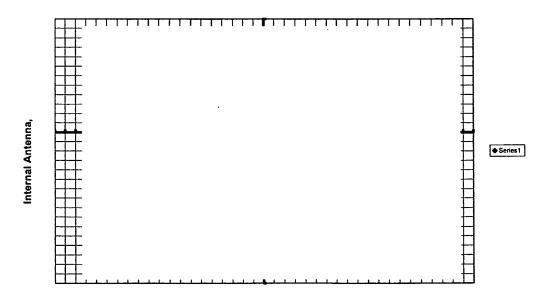
4.6.1.7 <u>RESULTS</u> **PASS**

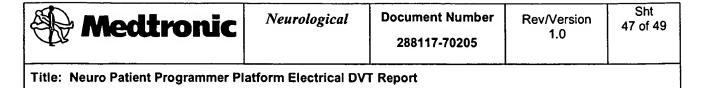
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4.6.1.7.1 Internal Antenna Map @

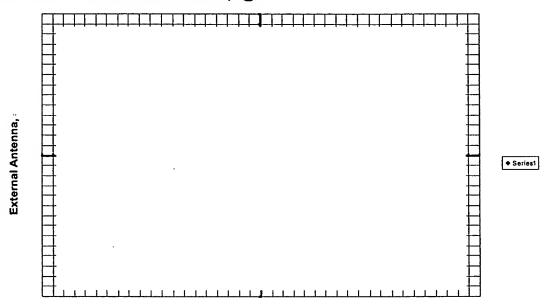


4.6.1.7.2 Internal Antenna @

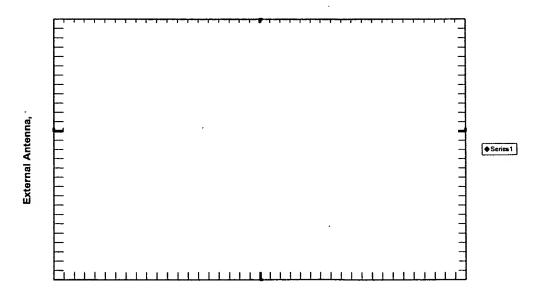




4.6.1.7.3 External Antenna Map @



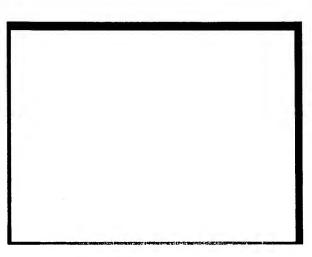




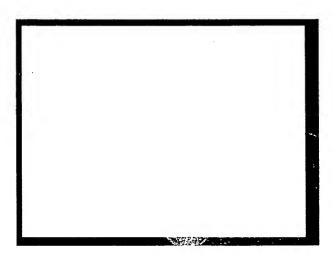
4.6.1.7.5 Photo of test fixture showing

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in this photo.



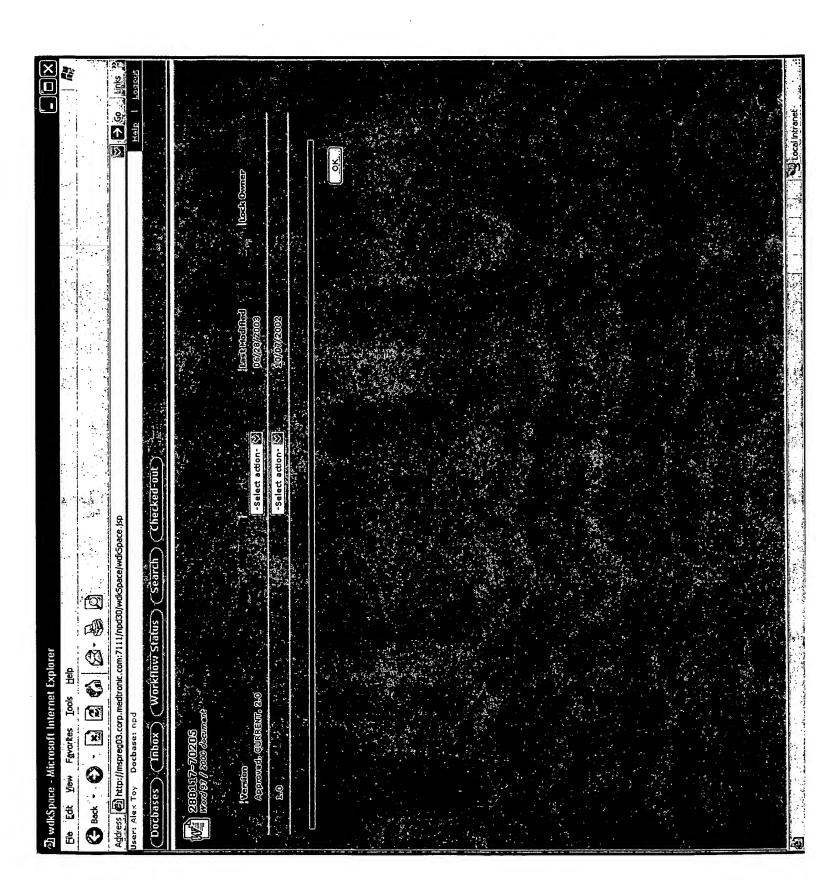
4.6.1.7.6 Photo of



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5 COMPLETION

This paragraph concludes this test specification.



DVT Test Data for 288117-70020

Test Path #1 from DVT Plan 288117-70020 Section 7.0

Test Path #1

DVT Pre-Test Performed to verify operational units.

																		\sqcap					
NJD000149P	NJD000140P	NJD000139P	NJD000138P	NJD000080P	NJD000079P	NJD000078P	NJD000077P	NJD000037P	NJD000036P	NJD000035P	NJD000034P	NJD000033P	NJD000031P	NJD000028P	NJD000026P	NJD000025P	NJD000024P	NJD000022P	NJD000020P	NJD000019P	NJD000018P	Serial Number	
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	operational	Buttons
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	Audio	
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	LCD	
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	Battery contact Battery Door	
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	t Battery Door	
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	clock	Real time
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	Ā	
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	1	
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	Backlight Communication	
욧	웃	웃	웃	웃	웃	웃	웃	웃	웃	웃	웃	웆	웃	웃	웃	웃	웃	웃	웃	웃	웃	Results	

Testing performed by

Date:

23-May-02

288117-70183

EQUIPMENT:

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Page 1 of 29

SUMMERY SHEET

TECH:

Patient Programmer for Neuro devices.

DATE: 29 MAY 02 INITI. **PAR# 5365 TEST PLAN: 288117-70020**

INITIAL VISUAL & ELECTRICAL

×	O.K.	NJD000034P
×	0.K.	NJD000033P
×	O.K.	NJD000031P
×	O.K.	NJD000028P
×	O.K.	NJD000026P
×	O.K.	NJD000025P
×	O.K.	NJD000024P
×	0.К.	NJD000022P
×	O.K.	NJD000020P
×	O.K.	NJD000019P
×	0.K.	NJD000018P
did functional	VISUAL	SERIAL#
Requestor		

NJD000037P NJD000077P NJD000078P NJD000079P NJD000080P NJD0000138P NJD000149P NJD000140P NJD000139P 3-Jun O O O O O 00000

Exhibit D (cont.)

NJD000035P

RESULTS: NO ANOMALIES NOTED

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SUMMERY SHEET

Patient Programmer for Neuro devices.

DATE: 19-Jun-02 TEST PLAN: 288117-70020 euro devices. Life cycle of battery contacts and door, and external antenna jack.

Subject samples

					,,																		
NJD000140P NJD000149P	NJD000139P	NJD000080P	NJD000079P	NJD000078P	NJD000077P	NJD000037P	NJD000036P	NJD000035P	NJD000034P	NJD000033P	NJD000031P	NJD000028P	NJD000026P	NJD000025P	NJD000024P	NJD000022P	402000DLN	4610000GFN	4810000DLN	Serial Number	number	288117-70020 test	
																				cycles	6.3.3		Battery Door
																				cycles	6.3.4		Battery External Contact Antenna
	<u></u>			ئــا	Ll	11	11	<u> </u>	اببا	اسا	!		L	لــــا	ليبا	L				cycles	6.3.5		xternal
																				Tested by:			
																				Length	6.3.1		Dimension
																				Width			ă ·
																				Ŧ			
																				02.	6.3.2		Weight w/o batteries
																				02.			Weight w/o Total batteries 2 AA batteries Weight
																				0Z.			Total Weight

Exhibit D (cont.)

Average

288117-70183

Test Path #1

Std Dev Dimensions per print 502814

EQUIPMENT:

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SUMMERY SHEET

PAR# 5365 TEST PLAN: 288117-70020

Patient Programmer for Neuro devices. Storage Temperature paragraph 6.2.2 of test plan.

19-Jun-02 All Functional Testing done per 6.1 except backlight and IR port.

Subject samples to low temp. storage of degrees F for hours then degrees F for hours.

Functional test samples post each temperature storage.

Date: Complete	NJD000149P	NJD000140P	NJD000139P	NJD000138P	NJD000080P	NJD000079P	NJD000078P	NJD000077P	NJD000037P	NJD000036P	NJD000035P	NJD000034P	NJD000033P	NJD000031P	NJD000028P	NJD000026P	NJD000025P	NJD000024P	NJD000022P	NJD000020P	NJD000019P	NJD000018P	Serial #
18-Jun 18-Jun 19-Jun		. 1		. 1	•												. 1	l				-	Functional
19-Jun																<u>.</u>							Functional

NOTES: C ₽ ₽

Results:

288117-70183

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EQUIPMENT:

Test Path #1

SUMMERY SHEET

PAR# 5365 TEST PLAN: 288117-70020

Patient Programmer for Neuro devices. Operating Temperature paragraph 6.2.1 of test plan.

DATE: 4-Jun-02 All Functional Testing done per 6.1 except backlight and IR port.

Subject samples to Low temp. storage of degrees F for hours then degrees F for hours.

Serial # [Low temp. | Functional | High Temp. | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functional | Functiona

																						·		
20.	Date: Complete	NJD000149P	NJD000140P	NJD000139P	NJD000138P	NJD000080P	NJD000079P	NJD000078P	NJD000077P	NJD000037P	NJD000036P	NJD000035P	NJD000034P	NJD000033P	NJD000031P	NJD000028P	NJD000026P	NJD000025P	NJD000024P	NJD000022P	NJD000020P	NJD000019P	NJD000018P	Serial #
7	4-Jun																							Low temp.
	4-Jun																							Functional High Temp.
	5-Jun					•																		ligh lemp.
	5-Jun											1	•			•				•	•			Functional
	L.	<u> </u>	<u> </u>			l	<u>. </u>	l	<u> </u>	<u> </u>		<u> </u>		<u> </u>			<u> </u>		L.	<u>l</u> _		ļ	<u> </u>	L

Results:

EQUIPMENT:

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288117-70183

SUMMERY SHEET

PAR# 5365 TEST PLAN: 288117-70020

Patient Programmer for Neuro devices.

DATE: 20-Jun-02 Thermal Shock paragraph 6.2.3 of test plan.

Subject samples to cycles of degrees F, I

Subject samples to cycles of degrees r, I

Dwell at each temperature for 1 hour. All Functional Testing done per 6.1 except backlight and IR port.

Thermal Functional Visual

					_	_								_	_				_				
NJD000149P	NJD000140P	NJD000139P	NJD000138P	NJD000080P	NJD000079P	NJD000078P	NJD000077P	NJD000037P	NJD000036P	NJD000035P	NJD000034P	NJD000033P	NJD000031P	NJD000028P	NJD000026P	NJD000025P	NJD000024P	NJD000022P	NJD000020P	NJD000019P	NJD000018P	Serial #	
																						Shock	merman
																						Testing	Functional
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NOTES:

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RESULTS:

EQUIPMENT:

288117-70183

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SUMMERY SHEET

TECH:

PAR# 5365 TEST PLAN: 288117-70020

Patient Programmer for Neuro devices.

21-Jun-02 Chemical Resistance paragraph 6.2.7 of test plan.

Subject samples to

		NJD000149P
l		NJD000140P
I		NJD000139P
1		NJD000138P
<u> </u>		NJD000080P
L		NJD000079P
1		NJD000078P
<u> </u>		NJD000077P
L		NJD000037P
l		NJD000036P
<u>L</u> .		NJD000035P
I		NJD000034P
i_ _		NJD000033P
		NJD000031P
		NJD000028P
<u> </u>		NJD000026P
L		NJD000025P
L		NJD000024P
L		NJD000022P
i		NJD000020P
L		NJD000019P
; : 	:	NJD000018P
	Testing	Serial #
Visual	Chemical	

Exhibit D (cont.)

RESULTS:

EQUIPMENT:

288117-70183

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Test Path #2 from DVT Plan 288117-70020 Section 7.0

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VT Pre-Test Performed to V	
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verify operational units.	
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Testing performed by

EQUIPMENT: |

Exhibit D (cont.)

Date:

23-May-02

288117-70183

Page 10 of 29

SUMMERY SHEET

PAR# 5365 TEST PLAN: 288117-70020

Patient Programmer for Neuro devices.

	×	0.K.	NJD000110P
			10000
	×	O K	N ID000109P
	did functional	VISUAL	SERIAL#
	Requestor		
INITIAL VISUAL & ELECTRICAL	INITIAL VISUAL	02	DATE: 29 MAY 02

	29-May	
×	O.K.	NJD000137P
×	O.K.	NJD000136P
×	O.K.	NJD000134P
×	O.K.	NJD000133P
×	O.K.	NJD000131P
×	O.K.	NJD000130P
×	O.K.	NJD000129P
×	O.K.	NJD000128P
×	O.K.	NJD000127P
×	O.K.	NJD000126P
×	O.K.	NJD000124P
×	O.K.	NJD000123P
×	O.K.	NJD000122P
×	O.K.	NJD000121P
×	O.K.	NJD000120P
×	O.K.	NJD000119P
×	O.K.	NJD000116P
×	O.K.	NJD000114P
×	O.K.	NJD000113P
×	O.K.	NJD000111P

Exhibit D (cont.)

RESULTS:

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Revision 2.0

SUMMERY SHEET

PAR# 5365 TEST PLAN:
Patient Programmer for Neuro devices.
DATE: 4-Jun-02 All Func TEST PLAN: 288117-70020

TECH:
devices.
Broad Band Random Vibration paragraph 6.2.4 of test plan.
All Functional Testing done per 6.1 except backlight and IR port.

Subject samples to

_								_	_	_	_	_						_	_	_			\neg
Date Completed 7-Jun	NJD000137P	NJD000136P	NJD000134P	NJD000133P	NJD000131P	NJD000130P	NJD000129P	NJD000128P	NJD000127P	NJD000126P	NJD000124P	NJD000123P	NJD000122P	NJD000121P	NJD000120P	NJD000119P	NJD000116P	NJD000114P	NJD000113P	NJD000111P	NJD000110P	NJD000109P	SERIAL#
7-Jun																							Back down
7-Jun																							Visual
7-Jun																							R. side dow
7-Jun																							Visual
7-Jun																							Top up
7-Jun																							Visual
13-Jun																							Functional
																							Observations

NOTES: Ç; ₽ }

EQUIPMENT: RESULTS:

288117-70183

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Revision 2.0

SUMMERY SHEET

PAR# 5365
TEST PLAN: 288117-70020
TECH: ROY POPE
Patient Programmer for Neuro devices.
Mechanical Shock paragraph 6.2.5 of test plan.
DATE: 20-Jun-02
All Functional Testing done per 6.1 except backlight and IR port.

Subject samples to

_														_	_					_	_	
NJD000137P	NJD000136P	NJD000134P	NJD000133P	NJD000131P	NJD000130P	NJD000129P	NJD000128P	NJD000127P	NJD000126P	NJD000124P	NJD000123P	NJD000122P	NJD000121P	NJD000120P	NJD000119P	NJD000116P	NJD000114P	NJD000113P	NJD000111P	NJD000110P	NJD000109P	SERIAL#
																						Front
-																					:	Back
																					:	Тор
																						Bottom
																				٠		Left side
																						Right side
																		•	•		:	Testing
							•															

NOTES: ₽ ₽

RESULTS:

EQUIPMENT:

288117-70183

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Test Path #3 from DVT Plan 288117-70020 Section 7.0

DVT Pre-Test Performed to verify operational units.

			_		_															_	_		
NJD000108P	NJD000107P	NJD000106P	NJD000104P	NJD000103P	NJD000102P	NJD000101P	NJD000100P	NJD000099P	NJD000098P	NJD000097P	NJD000096P	NJD000094P	NJD000093P	NJD000092P	NJD000089P	NJD000087P	NJD000086P	NJD000084P	NJD000083P	NJD000082P	NJD000081P	Serial Number	
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	operational	Buttons
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	Audio	
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	LCD	
×	×	×	×	×	×	×	×	×	×	×	×	×	. x	×	×	×	×	×	×	×	×	contact	Battery
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	Door	Battery
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	clock	Real time
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	≅	
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	Backlight	
×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	Backlight Communication	
웃	웃	ę	웃	웃	웃	웃	웃	ę	웃	웃	웃	웃	웃	웃	웃	웃	웃	웃	웃	S	R	Results	

Exhibit D (cont.)

Testing performed by

Date:

23-May-02

288117-70183

EQUIPMENT:

Page 14 of 29

PAR# 5365 TEST PLAN: 288117-70020

PAR# 5305

Patient Programmer for Neuro devices.

DATE: 29 MAY 02 INITIAL VISUAL & ELECTRICAL

Requestor Requestor

	29-May	Date: Complete
×	O.K.	NJD000108P
×	0.К.	NJD000107P
×	O.K.	NJD000106P
×	O.K.	NJD000104P
×	O.K.	NJD000103P
×	O.K.	NJD000102P
×	O.K.	NJD000101P
×	O.K.	NJD000100P
×	O.K.	NJD000099P
×	O.K.	NJD000098P
×	O.K.	NJD000097P
×	O.K.	NJD000096P
×	O.K.	NJD000094P
×	O.K.	NJD000093P
×	O.K.	NJD000092P
×	O.K.	NJD000089P
×	O.K.	NJD000087P
×	O.K.	NJD000086P
×	О.К.	NJD000084P
×	O.K.	NJD000083P
×	0.К.	NJD000082P
×	O.K.	NJD000081P
did functional	VISUAL	SERIAL#
Requestor		

Exhibit D (cont.)

RESULTS: NO ANOMALIES NOTED

288117-70183

288117-70183

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, days.

SUMMERY SHEET

RESULTS:				NOTES:	Date: Complete	NJD000108P	NJD000107P	NJD000106P	NJD000104P	NJD000103P	NJD000102P	NJD000101P	NJD000100P	NJD000099P	NJD000098P	NJD000097P	NJD000096P	NJD000094P	NJD000093P	NJD000092P	NJD000089P	NJD000087P	NJD000086P	NJD000084P	NJD000083P	NJD000082P	NJD000081P	SERIAL#		Subject	DATE:	Patient Programmer for Neuro devices	PAR# 5365
1		C=	8=	A=	3-Jun																								4	samples to	29-May-02 +	for Neuro devices	TEST
					3-Jun																								40	degrees F and	VII Functional Testin		TEST PLAN: 288117-70020
I	ଜୁ	F:	m m		4-Jun 4																									RH for days.	ng done per 6.1 e		020
					4-Jun 19-Jun 19															-										days. Test samples per request	All Functional Testing done per 6.1 except backlight and IR port.		
					19-Jun		•	•	•	•	•	•	•	•		.										•	•	' ്	ייי של	uest	port.		TECH:

EQUIPMENT:

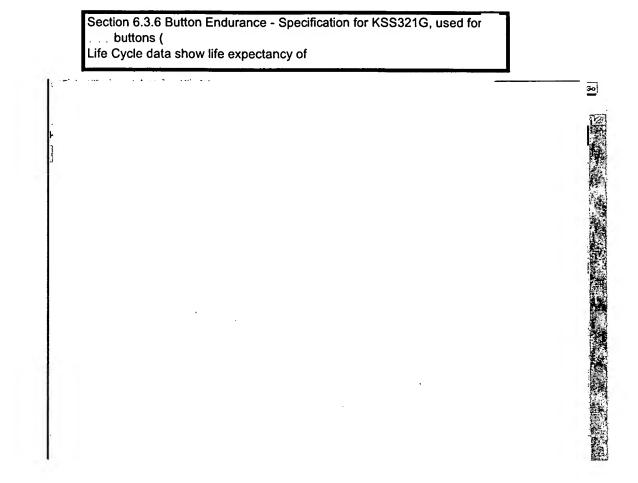
Test Path #3

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DVT Test Data for 288117-70020

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DVT Test Data for 288117-70020



DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.8 Flamability - Both top and bottom housings are made from

288117-70183

DVT Test Data for 288117-70020

DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.6 - Button Endurance - Specification for KSC621 top buttons (- Used for
Life Cycle data show life expectancy	
	

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<u>-</u>

Other Data DVT Test Data for 288117-70020 Revision 4.0

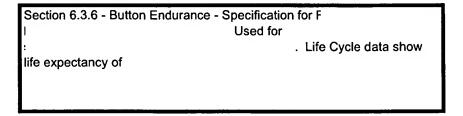
288117-70183

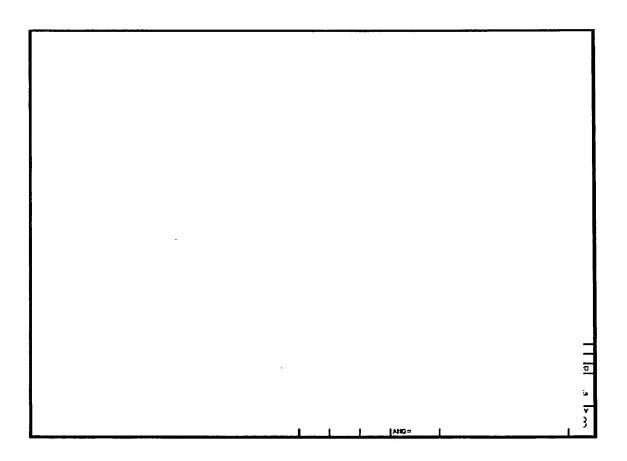
Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

DVT Test Data for 288117-70020





Other Data DVT Test Data for 288117-70020 Revision 4.0

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Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

DVT Test Data for 288117-70020

Section 6.3.7 Scratch resistance -	
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DVT Test Data for 288117-70020

DVT Test Data for 288117-70020

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